

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

S.S., et al.,)	CASE NO. 1: 12 CV 483
)	
Plaintiffs,)	JUDGE PATRICIA A. GAUGHAN
)	
vs.)	
)	
Leatt Corporation,)	Memorandum of Opinion and Order
)	
Defendant.)	

This is a products liability case. Five motions to exclude expert opinion testimony are pending before the Court: (1) Defendant's Motion to Exclude Proposed Expert Testimony by William F. Kitzes (Doc. 54); Defendant's Motion to Exclude Proposed Opinion by Richard L. Stalnaker (Doc. 59); Defendant's Motion to Exclude Proposed Opinion Testimony by Joseph Burton (Doc. 68); Defendant's Motion to Exclude Proposed Opinion Testimony by Carol Pollack-Nelson (Doc. 70); and Plaintiffs' Motion to Exclude Mitchell Garber as an Expert Witness (Doc. 72). For the reasons stated below, Defendant's motions to exclude the expert testimony of William F. Kitzes and Carol Pollack-Nelson are granted. The remaining motions to exclude expert testimony are all denied.

Background

Plaintiffs, sixteen-year-old Scott Scarvelli and his parents Timothy and Sheri Scarvelli, filed this lawsuit against defendant Leatt Corporation (Leatt) alleging products liability and other state law claims. Plaintiffs allege that Scott Scarvelli was seriously and permanently injured in February 2011 while using a Moto GPX neck brace manufactured by Leatt (the “Leatt Brace”) while he was riding a motocross motorcycle at the Ram Jam Sportsplex facility located in Lorain, Ohio. During a riding maneuver, Scott Scarvelli became separated from his motorcycle and landed on the dirt track surface. Plaintiffs allege that, as a result of using the Leatt Brace, Scott Scarvelli sustained spine and spinal cord injuries leaving him permanently paralyzed.

Plaintiffs’ complaint alleges claims against Leatt for “common law” negligence, product liability, misrepresentation, violation of Ohio’s deceptive consumer sales practices act, and loss of consortium.

Plaintiffs’ negligence claim alleges that defendants failed to exercise reasonable care in the design, testing, manufacture, modification, marketing, product warning, and distribution of the Leatt Brace and failed to prevent the Leatt Brace from creating an unreasonable risk of harm to Scarvelli. They allege that the Leatt Brace was “unreasonably and inherently dangerous to human health and safety, in particular to the spine and spinal cord, and became so, when applied to its usual, customary and intended use; and said defect existed at the time the Leatt Brace left the hands of the Defendant, and until it caused the spine and spinal cord injury and paraplegia, to the Plaintiff.” (Complt., ¶11.)

Plaintiffs’ products liability claim alleges: (1) the Leatt Brace “was defective in

testing, manufacture, formulation, and/or design that when it left the hands and control of said Defendant, it deviated materially from the industry performance standards, and/or differed from otherwise identical units manufactured to the same design formula”; (2) “the foreseeable risk of harm *i.e.*, spine and spinal cord injury associated with the design and/or formulation exceeded its benefits”; (3) “it was more dangerous than an ordinary and reasonably prudent consumer would expect when used in its reasonably foreseeable manner”; (4) “Defendant knew or should have known that the product was such to create an unreasonable risk of harm to consumers, and the Defendant failed to exercise reasonable care to warn of said risks”; (5) “Defendant . . . knew or should have known of the risks involved with the use of said product and failed to exercise reasonable care to provide inadequate warning to users of the product”; and (6) “it did not conform to representations of the Defendant that it was safe for use by consumers, which the Plaintiff relied upon.” (Complt., ¶¶ 17-22.) Plaintiffs allege that Leatt’s alleged conduct violates the Ohio Product Liability Act, Ohio Revised Code §§2307.72 through 2307.80.

The misrepresentation claim alleges that Leatt “made misleading statements and omissions about the safety of the Leatt Brace in its labeling, advertising, warnings, promotional materials and other marketing efforts” and “misrepresented the safety of the Leatt Brace and recklessly, intentionally and negligently misrepresented the quality of the product and concealed the adverse effects of the safety of the product to include but not limited to the failure to serve its intended purpose.” (Complt., ¶¶ 26-27.)

Plaintiffs’ fourth cause of action alleges that Leatt’s conduct “constitutes unfair deceptive consumer practices and unconscionable acts and practices” as defined in Ohio’s

Unfair Deceptive and Unconscionable Sales Practices Act. (Complt., ¶31.)

The fifth and sixth causes of action allege claims for loss of consortium on behalf of Timothy and Sheri Scarvelli. (Complt., ¶¶ 33-38.)

Plaintiffs also allege a claim for punitive damages (seventh cause of action).

On November 30, 2012, plaintiffs filed reports of nine proposed witnesses, including Joseph L. Burton, Richard L. Stalnaker, Carol Pollack-Nelson, and William F. Kitzes. (Doc. 47.) On February 4, 2013, Leatt filed its designation of witnesses and the expert reports of six proposed witnesses, including the expert report of Dr. Mitchell Garber. (Doc. 53-10.) Leatt moves to exclude opinions and testimony of plaintiffs' proposed witnesses Kitzes, Burton, Stalnaker, and Pollack-Nelson. Plaintiff moves to exclude the testimony of Garber.

Legal Standards on Expert Opinions and Testimony

Federal Rule of Evidence 702, which pertains to testimony by expert witnesses, was most recently revised by amendments that became effective on December 1, 2011 and provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

The Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509

U.S. 579 (1993) and its progeny require that the trial court act as a “gatekeeper” with respect to expert testimony under Federal Rule of Evidence 702. Pursuant to *Daubert*, the trial court must determine whether proffered expert testimony is both reliable and relevant. The Supreme Court stated in *Daubert* that:

Faced with a proffer of expert scientific testimony, . . . the trial judge must determine . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

Daubert, 509 U.S. at 592-93. The court stated that “[m]any factors will bear on [this] inquiry,” and there is no “definitive checklist or test.” Rather, the test for admissibility of expert testimony is a “flexible” one focused on the “principles and methodology” of the expert. *Id.* at 594-95. The court set forth the following non-exhaustive list of factors for trial courts to use in assessing the reliability of scientific expert testimony: (1) whether the expert's technique or theory can be or has been tested; (2) whether the technique or theory has been subject to peer review and publication; (3) the known or potential rate of error of the technique or theory when applied; (4) the existence and maintenance of standards and controls; and (5) whether the technique or theory has been generally accepted in the scientific community. *Daubert*, 509 U.S. at 593-94; *Avery Dennison Corp. v. Four Pillars Enterprise Co.*, 45 Fed.Appx. 479, 483 (6th Cir. Sept. 3, 2002). The trial court’s overall task is to ensure that a testifying expert “employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

The Sixth Circuit has acknowledged that “[t]he trial judge has considerable leeway in

deciding . . . how to go about determining whether particular expert testimony is reliable.” *U.S. v. Sanders*, 59 Fed.Appx. 765, 767 (6th Cir. March 7, 2003), citing *Kumho Tire*, 526 U.S. at 152. “As a baseline premise, ‘[i]n rulings on the admissibility of expert opinion evidence[,] the trial court has broad discretion and its rulings must be sustained unless manifestly erroneous.’” *Brainard v. American Skandia Life Ins.*, 432 F.3d 655, 663 (6th Cir. 2005). But the Sixth Circuit has developed further guidance by outlining a number of “[r]ed flags that caution against certifying an expert.” *Newell Rubbermaid, Inc. v. Raymond Corp.*, 676 F.3d 521, 527 (6th Cir. 2012), citing *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 177 (6th Cir.2009). These include “reliance on anecdotal evidence, improper extrapolation, failure to consider other possible causes, lack of testing, and subjectivity.” *Id.* In addition, if an expert's testimony was prepared solely for litigation, this may also be grounds for exclusion. *Id.*

Finally, the proponent of an expert bears the burden of demonstrating that the expert's testimony satisfies *Daubert*. *Nelson v. Tennessee Gas Pipeline Company*, 243 F.3d 244, 251 (6th Cir. 2001).

Federal Rule of Evidence 703 provides:

An expert may base an opinion on facts or data in the case the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.

Fed. R. Evid. 703.

Federal Rule of Evidence 705 provides:

Unless the court orders otherwise, an expert may state an opinion – and give the reasons for it – without testifying to the underlying facts or data. But the expert may be required to disclose those facts or data on cross-examination.

Fed. R. Civ. P. 705.

Fed R. Civ. P. 26 governs discovery and provides that the written report of an expert witness must provide contain all of the following information: (i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the facts or data considering by the witness; (iii) any exhibits that will be used to summarize or support the witness's opinions; (iv) the witness's qualifications; (v) a list of all other cases in which the witness has testified as an expert during the previous four years; and (vi) a statement of the compensation to be paid for the study and testimony in the case. Fed. R. Civ. P. 26(a)(2)(B).

Fed. R. Civ. P. 37(c)(1) provides that “[i]f a party fails to provide information or identify a witness as required by Rule 26(a) . . . , the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless that failure was substantially justified or is harmless.” Fed. R. Civ. P. 37(c).

Discussion

1. Defendant's Motion to Exclude Joseph L. Burton

Pursuant to Fed. R. Civ. P. 702 and *Daubert*, Leatt moves to exclude the proposed opinions of Joseph L. Burton, M.D., dealing with whether Scott Scarvelli's “incapacitating injuries are casually related to the performance of the Leatt neck brace.”¹ Burton is a doctor

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Other than Dr. Burton's “causation” opinions, Leatt does not challenge Burton's expert testimony. It asserts that Burton “apparently used medically reliable methods to describe Scott Scarvelli's physical injuries in the way pathologists customarily describe and document injuries at autopsy.” (Leatt Mem. at 2, n.3.)

and forensic pathologist with over thirty years of experience in forensic medicine, including as a Medical Examiner for DeKalb County, Georgia. His Curriculum Vitae also lists professional experience regarding kinematics and biomechanics in connection with head and spine injuries.

Leatt asserts in its brief that, included among the opinions Burton expresses in his report, are the following opinions on causation:

It is my opinion with reasonable scientific probability and certainty that the Leatt brace worn by Mr. Scarvelli was a direct and proximate cause of his catastrophic thoracic spine-spinal cord injury.

It is my opinion had Scott not been wearing the neck brace at the time of his incident on 2/13/11 he would not have suffered this catastrophic vertebral column injury.

The brace limited his head movement and increased axial loading of his spine.

Had the brace not been worn such increase would not have occurred and Mr. Scarvelli would have been better able to tuck and roll, avoiding the catastrophic axial force.

The design of the helmet, brace and strut virtually guarantees that a load will be concentrated on the upper thoracic spine area of the user.

Anyone putting on this brace and strut, having it rest against their back and having someone hold it tight against the spinous processes between the shoulder blades without a shirt on can clearly see that the strut will interfere with lateral rotation of the spine.

(Leatt Mem. at 2-3, citing Burton Report.)²

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Although not set out in Leatt's brief, Burton's report also includes the following opinions "concerning the kinematics of Mr. Scarvelli's crash that lead to his catastrophic thoracic spine injury":

1. When Mr. Scarvelli's front wheel impacted the berm it suddenly decelerated the bike. Mr. Scarvelli's body continued to move forward, his head striking the handlebars, glancing off, and his body continuing

Leatt contends Dr. Burton's causation opinions are inadmissible because his "Rule 26

forward and downward.

2. His shoulders struck the ground decelerating his torso and lower extremities creating sufficient force to cause the axial load compression fracture of his thoracic spine.

3. Previously quoted studies show that the Leatt brace increases axial load of the spine. Had the brace not been worn such increase would not have occurred and Mr. Scarvelli would have been better able to tuck and roll, avoiding the catastrophic axial force.

Not only is it important to consider what injury that Mr. Scarvelli sustained in understanding what happened to him, but it is also important to understand what injuries he did not sustain. He did not sustain any major deceleration injury to the organs of his chest or abdomen such as an aortic injury, cardiac injury, injury to the small and large intestines or momentum or impact trauma to the liver, spleen or other solid organs of the abdomen. He did not sustain a brain injury. . . .

The strut [of the Leatt Brace] is made of Kevlar and carbon fiber. It will afford substantial resistance to bending.

It will also supply substantial resistance to the spine. In other words, it will focus on a point, as in this case, approximately at the lowest level that the strut would be impinging upon the back which is around the T4/T5/T6 level of most adult male individuals. This would mean all of the vertebral column below the level of the strut will move in one direction whereas the column along the strut will be prevented from similar movement since the strut will abut the vertebra from the tip of the strut to the base of the helmet. Increases in axial load can not be dissipated through flexion bending of the spine since this is prevented by the strut. (Reference: Burton & Associates Thoracic Spine Injury Bibliography.)

The design of the helmet, brace and strut virtually guarantees that a load will be concentrated on the upper thoracic spine area of the user. Depending on the vertical impact force of the body to the ground and the motion of the body relative to the head and shoulders upon impact, severe injury to the thoracic spine will result at the T3 to T6 level.

(Burton Rep. at 13-14.)

report does not furnish logical foundations or lines of reasoning leading to rational conclusions,” and Burton’s opinions as to the consequences of wearing or not wearing a Leatt Moto GPX neck brace are not grounded in any actual physical or mechanical tests, measurements, calculations, medical literature, or other scientific methodologies meeting the threshold reliability requirement of Federal Rule of Evidence 702 and *Daubert*.

Leatt argues that, instead of reliable scientific or medical techniques, Burton relies in his opinions only on “simplistic pictures” to show that a significant relationship exists between the shape of the Leatt Brace and the vertebral levels of Scott Scarvelli’s thoracic fractures. Leatt refers to photos in Burton’s report which depict Burton wearing a Leatt Brace and another “unidentified young man” wearing a brace that is “overlaid with an illustration of the human spinal column.” (Leatt Mem. at 4, 5, 7.) Leatt argues that these “pictures alone” are not a “reliable methodology.” It asserts that other “specific protocols” exist “to measure either instability or fusions and describe loss of motion in the human spine regardless of cause,” but Dr. Burton conducted no actual physical or mechanical tests of his own regarding the Leatt Brace and thoracic spine injuries. (*Id.* at 6, 10.)

Leatt also argues that a “second set” of images depicted in Burton’s report, consisting of “two computer-generated images depicting alleged shearing action [on the spine] resulting in paraplegia,” is also lacking in “a reliable methodology.” Leatt refers to two computer-generated images appearing in Burton’s report purporting to depict the shearing action of the spine as well as normal spine anatomy. Leatt contends these computer-generated models are inadmissible and unreliable “because Burton did not supply any explanation for or [the] process used in creating his depiction of the shearing action on Scarvelli’s spine.” (*Id.* at 8.)

In addition, Leatt challenges Burton's opinion on the ground that "[s]cattered throughout [the] report are references to, and even express reliance on, two inadmissible categories of information: (1) other accidents or injuries, and (2) claims and reports by witnesses involved in unrelated litigation." (*Id.* at 11.) As to the second category, Leatt contends that Burton improperly relied on expert reports of Christopher Van Ee and Martha Bidez at SAFE Enterprise that were commissioned by plaintiff's attorneys in another case against Leatt, *Kemmer v. Leatt Corporation*, Case No. 5: 09 CV 84 (E.D. Ky.) Leatt contends that:

Every aspect of the reports commissioned by the plaintiff's attorneys in *Kemmer* prevents their re-use by Burton in this lawsuit: (1) neither Van Ee nor Bidez nor SAFE appear in plaintiff's initial disclosures . . . ; (2) neither Van Ee nor Bidez nor SAFE appear in plaintiff's identification of expert witnesses . . . ; (3) neither Van Ee nor Bidez nor SAFE are witnesses subject to cross-examination . . . (4) plaintiff's counsel are the sole source of the Van Ee, Bidez, and SAFE reports . . . ; (5) testimony by Burton about the Van Ee, Bidez or SAFE reports constitutes impermissible vouching for the truth of another person's statements . . . ; and, (6) because the Van Ee, Bidez, and SAFE reports were prepared solely for litigation involving a different accident and a different physical injury, their opinions fail the "fit" requirements of FRE 702.

(*Id.* at 12-13.)

Leatt also contends Burton improperly uses "irrelevant, unreliable, and inadmissible information about other motocross accidents" to support his opinion by asserting in his report that others who were approximately the same physical size as Scott Scarvelli and who wore a Leatt Brace – Bobby Kemmer, Ryan Reddick, and Stephen Barrington – also sustained upper mid thoracic spine injuries in virtually the same location as Scarvelli. Leatt contends Burton "does not furnish a factual predicate to show the substantial similarity or relevance of these other accidents." (*Id.* at 13.)

Finally, Leatt challenges as "totally subjective" the portion of Burton's opinion

asserting that had Scott Scarvelli not been wearing the Leatt neck brace he would not have suffered the “catastrophic vertebral column injury” he sustained. Leatt asserts that Burton offers no source or authority for this notion, but instead relies exclusively on his own anecdotal experience as a motorcycle rider that Scarvelli would have been better able to “tuck and roll” had he not been wearing the Leatt Brace at the time of his accident. (*Id.* at 14.)

Plaintiffs contend Burton’s causation opinions were based on reliable methodologies. Plaintiffs dispute Leatt’s contention that Burton’s opinions were based only on “simplistic pictures.” Plaintiffs contend the “simplistic pictures” Leatt criticizes are actually “surrogate studies” Burton performed “to test his hypothesis that the Leatt Brace’s thoracic strut restricts the ability of the spine to rotate in the areas which it comes in contact with, specifically the T-4 and T-6 vertebrae.” Thus, plaintiffs contend that Burton did perform some testing in developing his causation opinions (although they do not dispute that Burton did not perform physical or mechanical testing of his own other than these “surrogate studies”).³ Plaintiffs also dispute Leatt’s contention that Burton’s causation opinions were derived solely from these surrogate studies, asserting that Burton also relied on a host of sources of information allowed by the federal rules of evidence in forming his opinions, including testing and studies done by others and Leatt itself.

In particular, plaintiffs contend that Burton properly relied on the expert reports of biomechanical engineers Bidez and Van Ee in forming his opinions. Plaintiffs assert that “the

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Plaintiffs assert that “while Burton . . . [was] able to rely on studies concerning the established principles relating to the way the human spine works, it would be impossible to perform a test that exactly replicates Scott Scarvelli’s accident sequence” as the “only way to do so would be to use a human being, which would be grossly irresponsible and against all notions of scientific ethics based on the high likelihood of injury.” (Pltf. Opp. at 13.)

importance of these expert reports and opinions . . . regarding the Leatt-Brace's propensity to cause axial loading is unmistakable,"⁴ and they contend that Burton may properly rely on the relevant reports despite Leatt's objection that Van Ee and Bidez are not subject to cross examination in the case. Plaintiff rely on the language of Federal Rule of Evidence 703 itself, which provides that: "An expert may base an opinion on facts or data in the case the expert has been made aware of or personally observed" and that "[i]f experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted." Fed. R. Evid. 703. Plaintiffs assert that the "[s]tudies, testing, and opinions of other qualified individuals in their same field are the kinds of things that biomechanical engineers reasonably rely upon regularly as bases for forming their opinions." (Pltf. Opp. at 7.) Plaintiffs dispute Leatt's position that Burton's reliance on Van Ee's and Bidez's reports "constitutes impermissible vouching for the truth of another statements" because all of the cases Leatt cites in support of this argument stand for the proposition that an expert cannot be the mouthpiece of an expert from a "*different field of expertise*." But plaintiffs assert that "[g]iven the fact that Burton, Bidez, and Van Ee are all biomechanical experts there appears to be no reason for Leatt to make this

⁴Burton noted the relevance of these experts' opinions in his report:

I have previously stated this in the body of this report that virtually all vertebral column injuries start with axial load. The greater the axial load the more likely that the column will fail in some manner as its loads continue to be applied. The testing by others shows that with the strut and the Leatt brace in place that the axial load increases in some studies up to 75 percent.

(Report at 14.) It is Burton's opinion that the Leatt Brace greatly increases the chances for axial loading injury.

argument.” (*Id.* at 12) (emphasis in original.)

Plaintiffs dispute all of Leatt’s other bases for objecting to Burton’s reliance on Van Ee’s and Bidez’s reports, asserting: “no case or statute” supports Leatt’s position that Burton is prevented from relying on the reports because neither Bidez nor Van Ee appear in plaintiffs’ initial disclosures or witness list; the fact that Burton obtained the reports through counsel “does not deem them an improper basis for Dr. Burton’s opinions” as the reports were not the “only methodology” Burton employed to reach his opinions, the reports are highly relevant to the issue of axial loading presented in this case, and Burton explained the relevance of the reports to this case in detail in his report; finally, the reports are relevant to the accident in this case despite the fact that the reports were prepared in the context of litigation involving a different accident and injury because the reports address the issue of the Leatt Brace’s propensity to cause axial loading, which is at issue here.

Plaintiffs further point out that in reaching his causation opinions, Dr. Burton relied on the same testing that Leatt and its own experts “relied on in developing its own product,” citing documents produced by Leatt in discovery regarding “SABS Testing” and a document entitled “Thoracic Injury Assessment for the Leatt Moto GPX Brace.” (Pltf. Opp. at 14-15.) Plaintiffs contend Leatt’s testing also supports Dr. Burton’s position that the Leatt Brace transfers force to the T6-T7 levels of the spinal column, preventing it from rotating in an accident like Scott Scarvelli’s thereby resulting in shearing fracture. (*Id.* at 15-16.)

Finally, in addition to all of the above, plaintiffs assert that Burton relied on “a whole host of other items an expert would normally rely on in forming an opinion,” including:

medical and radiology records of Scott Scarvelli, the Leatt Brace User Manual and other Leatt materials turned over in discovery in the *Barrington* matter,

deposition testimony of Scott, Tim, and Sherri Scarvelli, deposition testimony of Dr. Christopher Leatt (which Dr. Burton gives two pages of explanation as to what portions he finds relevant), along with all Leatt-brace static and drop testing with videos. Finally, Dr. Burton references other independent studies concerning the human neck and spine, most notably the Cost 327 Study, which is attached as an Appendix of his report.

(Opp. at 17.)⁵

In sum, plaintiffs contend that Dr. Burton's causation opinions were derived from "much more" than merely simplistic pictures, but were derived from available information routinely used by experts and allowed by the federal rules of evidence. Plaintiffs contend that "Leatt may disagree with [Dr. Burton's] diagnosis" and may not agree with Dr. Burton's theory of causation in this accident but that "the questions [Leatt] has concerning Dr. Burton's opinions should be fleshed out at trial, during cross-examination. The test of admissibility is not whether an opinion is demonstrably correct, but rather whether the opinion is based on valid reasoning and reliable methodology." (Pltf. Opp. at 5.)

Upon review, the Court is satisfied that Burton's causation opinions meet the requirements of *Daubert* and Fed. R. Evid. 702. As the Supreme Court held in *Daubert*, an expert has a "wide latitude to offer opinions" and an expert's opinion need not be based on "first-hand knowledge or observation." See *Brown v. Wal-Mart Stores, Inc.* Case No. 98-5965, 1999 WL 1111514, at *3 (6th Cir. Nov. 24, 1999), citing *Daubert*, 509 U.S. at 592. This "wide latitude" is "premised on an assumption that the expert's opinion will have a

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Plaintiffs also dispute Leatt's contention that the computer-generated images depicted in Dr. Burton's report are inadmissible because Burton did not explain the process and data used to generate them, contending that the images are proper because they are not used to demonstrate any fact at issue in the case or that Scott Scarvelli's injury happened in any particular way but are simply used to assist the jury in understanding what a shearing fracture looks like. (See Pltf. Opp. at 6.)

reliable basis in the knowledge and experience of his discipline.” *Id.* Thus, Dr. Burton is not required to have performed his own independent testing to determine or measure the effect on the spine of wearing the Leatt Brace for his causation opinions to be admissible.

Further, plaintiffs have sufficiently demonstrated that Burton’s causation opinions were not based merely on “simplistic pictures” as Leatt argues, but instead were based on an adequate foundation of expertise, documentation, available studies and testing, and personal experience. Plaintiffs have sufficiently demonstrated that Burton’s opinions were based on his assessment of the Leatt Brace as observed in his surrogate studies, together with other existing information about the relationship between the Leatt Brace and axial loading, including expert reports of biomechanical engineers Van Ee and Bidez and Leatt’s own product testing.

The Court finds that Burton’s causation opinions are not inadmissible because they are based in part on the reports of Van Ee and Bidez. On this point, the Advisory Committee Notes to Fed. R. Evid. 702 specifically state that:

expert testimony [must] be based on sufficient underlying “facts or data.” The term “data” is intended to encompass the reliable opinions of other experts.

Fed. R. Evid. 702 advisory committee’s note.

Further, Fed. R. Evid. 703 is explicit that an expert may base his opinion on “facts or data . . . the expert has been made aware of or personally observed” and that “[i]f experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they [the facts or data] need not be admissible for the opinion to be admitted.”

Leatt cites cases standing for the proposition that *Daubert* does not allow an expert “to

be the mouthpiece of a scientist in a different specialty,” for example, a “theoretical economist . . . would not be allowed to testify to the findings of econometric study conducted by another economist if he lacked expertise in econometrics and the study raised questions that only an econometrician could answer.” *Dura Automotive Systems of Indiana, Inc. v. CTS Corporation*, 285 F.3d 609, 614 (7th Cir. 2002). However, Dr. Burton does not lack knowledge or expertise in the biomechanics of spine and spinal cord injuries as assessed by Van Ee and Bidez. To the contrary, plaintiffs have persuasively shown that Van Ee’s and Bidez’s reports are sufficiently within Dr. Burton’s domain of expertise (*i.e.*, assessing the biomechanics of spine and spinal injuries) such that Dr. Burton would reasonably rely on their opinions for purposes of Fed. R. Evid. 703.

Finally, while Leatt contends that specific computer-generated images appearing in Dr. Burton’s report lack adequate foundation, even assuming that the computer-generated images would be inadmissible at trial, this does not demonstrate that Burton’s causation opinions on the whole are completely inadmissible.

The Court finds Dr. Burton’s testimony admissible. Defendant’s motion to exclude the testimony of Joseph Burton is therefore denied.

2. Defendant’s Motion to Exclude Richard L. Stalnaker

Plaintiffs have submitted an eleven page expert report from Dr. Richard L. Stalnaker, an engineer with forty years of experience as a safety design manager with particular experience studying head, neck, and spine injuries. Like Dr. Burton, Dr. Stalnaker opines that the shearing fracture to Scott Scarvelli’s spine during his accident was caused by the Leatt Brace.

Stalnaker asserts in his report that his “Engineering analysis of the accident which took place on February 13, 2011, and the ability of the Leatt brace to protect the neck and upper torso; is based on the laws of physics.” (Stalnaker Rep. at 4.) Stalnaker identifies the sources of information he reviewed in preparing his report, including Scott Scarvelli’s medical records; depositions in the case; “Production Documents, Interrogatories, videos, etc.” produced by Leatt in discovery in the case; material provided by Dr. Bidez, SAFE, and Mr. Smith for *Kemmer v. Leatt*; pertinent reconstruction information provided by Rick Sanford; pertinent medical and biomechanical information provided by Dr. Joseph Burton; and Stalnaker’s personal inspection and photographs of the helmet and brace worn by Scott Scarvelli during the accident. (Stal. Rep. at 5.)

Stalnaker asserts that his inspection of the helmet and brace worn by Scarvelli at the time of the accident shows that Scarvelli’s head was in flexion during the accident and as he attempted to tuck and roll. Stalnaker states his opinion that:

When something is bent, it produces tension stress on the outside arc of the bend and compression force on the inside arc of the bend. In Mr. Scarvelli’s accident, the bending motion of his spine alone may not have provided sufficient tension or compressive forces to cause the fracture. However, when combined with the axial load maintained by the brace, the additional compression force to the anterior thoracic spine caused the vertebrae to fail and fracture.

The Leatt neck brace is highly resistant to bending and rotation. If the movement of the body during the accident includes a rotation or bend, this movement will be focused in a single point located just below the resistance. With the Leatt brace, this focal point is just below the strut. Dr. Burton’s surrogate photos from his Biomechanical analysis show that on most adult males, this focal point of rotation is going to be in the T4 to T6 level of the spine.

Mr. Scarvelli had been riding motocross since the age of three. It would have been an automatic reflex for him to perform the tuck and roll maneuver in an

accident of this kind if the Leatt brace had allowed it. During the tuck and roll maneuver, the spine bends in degrees, a few at a time, deflecting the forces away from the spine and adding additional degrees of flexion as the spine binds. If the proper execution of this maneuver is restricted, the forces will focus at the lowest point below the resistance, which in the case of the Leatt brace is the single point below the strut of the brace.

It is my opinion that had Mr. Scarvelli not been wearing the Leatt Brace, his spine would have bent gradually deflecting the forces and dissipating any axial load. Even if Mr. Scarvelli had not been able to make a conscious decision to maneuver into a roll to deflect the forces, the configuration of his fall and the articulation of vertebrae would have compressed his body naturally into the rolling movement. It was the focal point of the forces at the single point caused by the Leatt brace that caused the severity of Mr. Scarvelli's injury. Had Mr. Scarvelli not been wearing the brace, the bending would have occurred in a rolling motion of deflection rather than a focused bend and he would not have received this injury. Based on the kinematics and location of this accident, Mr. Scarvelli, more likely than not, would not have suffered any serious injury.

Conclusion:

I have come to the following conclusion, based on the above sources of information, my analysis of the accident and my forty years of experience, within a reasonable degree of scientific probabilities.

There is no indication that any force in an accident is absorbed by the brace. The forces are simply redirected into the shoulders and the upper thoracic vertebrae. . . .

Testing results that were available to Leatt show that the Leatt brace increased the axial load in some impact conditions. The chance of a spinal injury is greatly increased by a higher axial load, leading to the conclusion that use of the brace actually increases the risk of injury. Leatt, knowing that an increased axial load was being redirected, failed to conduct testing to determine the consequences of the increased forces to the thoracic area of the body for injury risk.

The tuck-and-roll maneuver is used by most sport that may involve a fall to improve neck force parameters on impact. It is obvious by the damage to the helmet and the brace that the impact between the two prevented Mr. Scarvelli from performing this maneuver for his safety.

The Leatt brace is defective and unreasonably dangerous in that it fails to absorb any force, creates an increased axial load, and hinders the wearer from

performing safety maneuvers to prevent injury. The design of the brace and strut focus a bending/twisting point just below the strut of the brace virtually guaranteeing that a load is concentrated on the upper thoracic spine.

The Brace is defective in design and formulation in that the foreseeable risks associated with the design exceed the benefits. The increased risk in injury to the thoracic spine far exceeds the benefit of the minimal, if any, protection to the cervical spine. . . .

The Brace was also defective due to Inadequate Warning. . . .

The Brace was again also defective in that Leatt failed to conform to its representations. Leatt claims that the brace will protect the neck but it fails to even do that. . . .

If Mr. Scarvelli had not been wearing the Leatt brace, his spine would have bent gradually deflecting the forces and dissipating any axial load. Based on the kinematics and terrain of this accident, Mr. Scarvelli most likely would have suffered no serious injury if he had not been wearing the brace.

(Stal. Rep. at 9-11.)

Leatt contends Stalnaker's opinions should not be permitted at trial because they are inadequately disclosed under Fed. R. Civ. P. 26 and are unreliable under Fed. R. Evid. 702 and *Daubert*.

First, Leatt contends Stalnaker's report is insufficient to satisfy Rule 26's disclosure requirements and should be excluded because the report does not set forth all "facts and data" legally required under Rule 26; specifically, Stalnaker does not disclose the "testing results that were available to Leatt" on which Stalnaker relied in rendering his opinion. Leatt argues that it cannot "cross-examine Stalnaker on [his] accusation" that testing results available to Leatt show that the Leatt Brace increased the axial load in some impact conditions "because he does not identify the 'testing results' he claims to be referencing." (Leatt Mem. at 4.)⁶

⁶

Leatt also contends that Stalnaker improperly relied on "materials the Rule of

Second, Leatt contends Stalnaker's testimony is inadmissible because he failed to supply "any discernible reasoning process" to support the conclusion expressed in his report that "the Leatt brace . . . fails to absorb any force." Leatt argues:

Stalnaker offers this conclusion without any discernible reasoning process, and this is a fundamental flaw in any Rule 26 submission. A report that supplies only a bottom line opinion is automatically excludable under Rule 37(c)(1). Stalnaker's opinion also fails to meet the admissibility threshold of FRE 702 because he did not use – and his Rule 26 report does not contain – any reasoning or methodology that would give this assertion the requisite 'reliable foundation.' A discernible reasoning process connecting the witness's conclusions to the underlying facts is absolutely essential. A report lacking 'a line of reasoning arising from a logical foundation' falls short of Rule 26(a)(2)(B). *Brainard v. American Skandia Life Ins.*, 432 F.3d 655, 664 (6th Cir. 2005).

Leatt emphasizes that Stalnaker "does not have any empirical data to support his claim about the alleged ineffectiveness of the Leatt Brace" and admitted that he conducted no testing of his own. (*Id.* at 7.)

Evidence do not permit," specifically, "Material provided by Dr. Bidez, SAFE, and Mr. Smith for *Kemmer v. Leatt*." (Leatt Mem. at 4.) As it did in connection with its motion to exclude the causation testimony of Dr. Burton, Leatt argues with respect to Stalnaker's opinion that:

Every aspect of the Bidez/SAFE report commissioned by the plaintiff's attorneys in *Kemmer* prevents its re-use here: (1) neither Bidez nor SAFE appear in plaintiff's initial disclosures . . .; (2) neither Bidez nor SAFE appear in plaintiff's identification of expert witnesses . . .; (3) neither Bidez nor SAFE are witnesses subject to cross-examination . . . (4) plaintiff's counsel are the sole source of the Bidez/SAFE report . . .; (5) testimony by Stalnaker about the Bidez/SAFE report would be vouching for the truth of another person's statements . . .; and, (6) because the Bidez/SAFE report was prepared solely for litigation involving a different accident and a different physical injury, it fails both the fit and reliability prongs of FRE 702.

(Leatt Mem. at 5.)

Third, Leatt contends Stalnaker's testimony should be excluded because his report contains "no methodology of any kind – no test, experiment, calculation or model – to either prove or disprove his causation claim" that the "Leatt brace creates . . . an increased axial load" and "substantially increases the risk of spinal column injury, which due to the design of the brace and thoracic strut, results in a failure on the thoracic spine at the focal point of rotation which is where the thoracic strut ends." (*Id.* at 8.) Leatt contends Stalnaker's report gives "no clue" as to how Stalnaker reached the conclusion that the brace's design caused the thoracic spine injury, and it asserts that Stalnaker's opinion on this point contains none of the other traditional hallmarks of scientific reliability – testing, peer review, information as to error rate, or general acceptance in the scientific community. (*Id.* at 12.)

Finally, Leatt contends that since Stalnaker "failed to use any reliable methodology to assess the allegedly negative effect" of wearing the Leatt Brace, Stalnaker "cannot logically support his claim" expressed in his report that Scarvelli "would have suffered no serious injury" wearing no neck brace at all. On this point, it asserts:

Stalnaker cannot use the accident itself to illustrate his thesis about the consequence to Scarvelli of not wearing a neck brace since this is an event that did not occur. And Stalnaker offers nothing else to show that this opinion is reliable.

(*Id.* at 13.)

Plaintiffs, however, contend Stalnaker's testimony is proper under Fed. R. of Evid. 703 and *Daubert*. They assert that, in rendering his opinions in this case, Stalnaker relied on the same data and information that plaintiffs' own expert (Dr. Mitchell Garber) relied upon in rendering his opinions in the case, including medical records, medical literature, the accident reconstruction of plaintiffs' expert Richard Stanford, and "Leatt documents provided in

discovery,” including “Leatt testing, BMW testing and SABS testing.” (Opp. at 4.) Plaintiffs contend this is a sufficient basis to satisfy the standards of admissibility under Fed. R. Civ. P. 703. Plaintiffs emphasize the Supreme Court’s statements in *Daubert* that an expert is permitted “wide latitude to offer opinions” based on the premise that the expert’s opinion “will have a reliable basis in the knowledge and experience of his discipline.” (Opp. at 11-12).⁷ Plaintiffs contend this characterizes Stalnaker’s “methodology” here, asserting that Stalnaker’s “opinions are rooted in physics and the corresponding formulas and mathematics associated with the field and [are] not reliant upon physical testing.” (*Id.* at 14.) And plaintiffs assert that “[w]hile [Stalnaker] may not have witnessed the testing produced by Leatt through discovery or that done in the studies and other expert reports he relied on, he is permitted to interpret this data and use it to form his opinions based on his knowledge and experience in his field of expertise.” (Opp. at 12.) According to Stalnaker, the effect of wearing the Leatt Brace was to increase the axial and compressive forces applied to Scott Scarvelli’s spine during his accident and cause his spine to shear.⁸

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Furthermore, plaintiffs contend it is disingenuous for Leatt to attempt to hold plaintiffs’ expert to a higher standard than its own expert, Dr. Garber, who also did not conduct any of his own testing.

8

Plaintiffs assert that Dr. Stalnaker repeatedly stated during deposition that he was prepared to illustrate the forces that occurred based on the laws of physics at trial. They assert:

In his deposition, Dr. Stalnaker, when asked to show evidence that the Leatt brace guided the forces in this accident, responded the forces ‘have to follow the laws of physics and [he] can certainly, and will at trial if asked to, draw the load paths’ of these forces. Dr. Stalnaker also testified in his deposition that he could document the differen[ce] in the range of motion between wearing the brace and not wearing the brace. Dr.

Plaintiffs contend that the jury should be entitled to judge “who is more qualified and who is more persuasive” to opine on the information that both parties’ experts have considered -- Stalnaker, a leading expert in the field “who conducted cadaver testing and research in [a] spine injury program, and impact studies and research on the head, or the Defense expert Dr. Garber, who has never conducted any such testing.” (*Id.* at 9.)

Upon review, the Court denies Leatt’s motion to exclude proposed opinion testimony of Dr. Stalnaker. Like the report of Dr. Burton, Stalnaker’s report satisfies the basic requirements of Fed. R. Civ. P. 26(a)(2)(B) and Fed. R. Evid. 702. The report sets forth the information on which Stalnaker relied in preparing his opinions, including “Production Materials” produced by Leatt in the case. This is sufficient to disclose that Stalnaker relied on Leatt’s testing information that was disclosed in discovery. The report also satisfies the requirement of Fed. R. Evid. 702 that the testimony be the product of sufficiently reliable principles and methodology. Although Dr. Stalnaker does not specifically illustrate in his report how the laws of physics operated, he testified that he is prepared to illustrate at trial how the forces of the laws of physics applied in the accident, and there is no dispute that Dr. Stalnaker has expertise in this area. Universally accepted laws of physics would constitute “reliable principles and methods” upon which an expert may base an opinion within the meaning of Fed. R. Civ. P. 702. Further, as discussed above in connection with the testimony of Dr. Burton, the federal rules of evidence do not require that an expert base his opinion on

Stalnaker is fully prepared to draw out the load paths of the forces in this accident, apply these forces to the universally accepted laws of physics and prove that the Leatt brace directly caused Mr. Scarvelli’s spine injury.

(Pltf. Opp. at 20-21.)

his own empirical testing, but may rely on the work of others if experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion. Experts in Dr. Stalnaker's field would reasonably rely on the information Dr. Stalnaker considered and reviewed. The report is based on a sufficiently reliable methodology in that Stalnaker reviewed pertinent information and materials that existed and applied his expertise regarding the laws of physics and concluded that the Leatt-Brace increased the axial load on Scott Scarvelli's spine and caused his spine to shear.

Leatt contends that its own biomechanical expert, Dr. Erick Knox, conducted the testing that Dr. Stalnaker suggests is impossible⁹ and supplied a "detailed critique of Stalnaker's work, exposing in the process the lack of scientific support for Stalnaker's conclusions." (Leatt Rep. at 3.) While Leatt is entitled to challenge Dr. Stalnaker's conclusions and opinions regarding the Leatt Brace and the forces of the law of physics at trial (including whether it is possible to test the brace) through the testimony and testing of Dr. Knox and otherwise, the Court does not find that Dr. Stalnaker's testimony is inadmissible on the ground that it is not "reliable" within the meaning of Fed. R. Evid. 702.

The Court finds Dr. Stalnaker's opinion testimony admissible under *Daubert* and Fed. R. Evid. 702. Defendant's motion to exclude Stalnaker's proposed testimony is denied.

9

Dr. Stalnaker contends there are no test dummies available to measure axial loads on the thoracic spine. (See Pltf. Opp. at 15.) His position is that there "are some computer models for the human thoracic spine, but the dummies, the Hybrid III, even some of the more complex dummies, the EURODISs and some of the newer ones, don't actually have thoracic spines. It's all a single molded or fabricated piece of metal, and so there is no ability on currently-available dummy models to measure loads on the thoracic spine, and there is no criteria by which to judge those loads, even if you could measure them."

3. Defendant's Motion to Exclude Carol Pollack-Nelson

Leatt moves to exclude the proposed opinion testimony of plaintiffs' expert Carol Pollack-Nelson, Ph.D., a "human factors psychologist" specializing in the field of consumer product safety. From 1988 through 1993, Dr. Pollack-Nelson was employed by the U.S. Consumer Product Safety Commission in the Human Factors Division. Since 1994, she has been working independently as a human factors consultant.

In her report, Pollack-Nelson sets forth the following "human factors" opinions:

1. Leatt's marketing materials caused Tim Scarvelli to believe that the Leatt-Brace would reduce Scott's risk of severe injury or death in a motocross accident and that the Leatt-Brace was as necessary as a helmet.
2. Leatt's advertising materials are misleading and deficient in that they not only exaggerate the extent to which the brace was tested, but also do not inform consumers of the serious limitations of testing and of the brace. As a result, the Scarvellis did not know that by wearing the Leatt-Brace, Scott was at risk for serious injury to the thoracic spine.
3. The Defendant knew, or should have known that the Leatt-Brace can restrict movement and cause injury. Leatt should have addressed these issues prior to releasing the brace into the market. Furthermore, upon learning of the thoracic spine injuries suffered by Leatt-Brace wearers, Leatt should have immediately recalled the brace from consumers and stopped sale.
4. Mr. Scarvelli's failure to fully read warnings was to be expected and is common behavior for consumers. Furthermore, even if Mr. Scarvelli had fully read the warnings, it would not have changed either his perception of the product or the outcome of Scott's accident.

In addition, Pollack-Nelson sets forth the following "conclusions" in her report:

The Leatt-Brace is not only defective for causing permanent injury to Scott Scarvelli's spine, but it is egregiously so because it was a piece of safety equipment that fostered a false sense of security. It is reasonable for consumers to expect safety gear will reduce their risk, not increase it. The Leatt-Brace instilled a false sense of security in the Scarvellis who decided to have their sons wear the brace as a result of information gained through Leatt's very extensive marketing and promotional campaign. While warnings

provided with the product include the standard caveats, Leatt's marketing and advertising of the product overshadow such warnings. Furthermore, Leatt's warnings did not elucidate the specific injuries that might result from wearing the brace. As a result, the Scarvellis believed Scott was safer if he wore the Leatt-Brace and that the brace could protect him from serious injury or death.

Consumer products should be tested and reasonably safe for their intended use (and reasonable unintended use). It is the responsibility of the manufacturer to conduct a risk assessment in the design phase. Identified hazards should be addressed prior to the product's entry into the market. In the event that product hazards do not come to light until after the product is in the market, such as from injury reports, then upon learning of serious injuries associated with its product, the manufacturer should take immediate action to ensure that other consumers do not suffer a similar fate. Leatt should have identified and addressed the serious hazards posed by its brace before the product was sold to consumers. Furthermore, upon learning of the catastrophic injuries suffered by riders who wore the brace Leatt should have taken immediate action to notify consumers and recall the brace, as well as stop future sales until the hazards were addressed.

From a human factors perspective, a defective product is one that presents a risk under normal and foreseeable use but for which that hazard is not apparent or known to the consumer

(Rep. at 14)

Leatt argues that Pollack-Nelson's proposed "advertising opinions" should be excluded because Pollack-Nelson admits that she does not know, or need to know, what of Leatt's actual advertising the Scarvellis actually read or saw. Leatt contends Pollack-Nelson's opinions are irrelevant because

Missing from Pollack-Nelson's Rule 26 disclosure is any methodology to: (1) identify the advertising that either Scott or Tim Scarvelli actually saw or read before obtaining Scott's brace in 2007; (2) demonstrate how they were deceived by any specific advertising; or (3) provide evidence of what Scott or Tim Scarvelli did or thought in reliance on this advertising.

(Leatt Mem. at 4.)

In addition, Leatt argues that, even if marginally probative, Pollack-Nelson's

advertising opinions run afoul of Fed. R. Evid. 403. They assert that it is “difficult to envision a greater waste of time than testimony from an industrial psychologist on the content of advertising that a plaintiff did not see” and that the “confusion likely to be engendered by such testimony is underscored by the fact that the single most influential piece of information for Scott Scarvelli’s father, Tim Scarvelli, was an unexpected Internet video [a video referred to in the briefs as the David Bailey video] that Leatt Corporation did not solicit, make, or distribute.” (*Id.* at 5.)

Further, Leatt contends that Pollack-Nelson’s specific opinions expressed in her report that the Leatt Brace “can restrict movement and cause injury” and that Leatt “should have immediately recalled the brace from consumers and stopped sale” are also excludable. Leatt points out that for purposes of her opinions, Pollack-Nelson merely assumed the existence of product defect. She admitted she “assum[ed] that Dr. Burton’s conclusions” in that regard were “correct.” (Leatt Mem. at 6-7.)

Plaintiffs contend that Pollack-Nelson’s advertising opinions are admissible regardless of the extent to which the Scarvellis relied on Leatt’s advertising and marketing materials, relying primarily on *Leichtamer v. American Motors Corp.*, 67 Ohio St.2d 456, 424 N.E.2d 568 (1981), in which the Ohio Supreme Court held that it was not error to admit evidence of a defendant’s commercial advertising for the purpose of “establish[ing] consumer expectation of safety and intended use” in a product liability case brought under Ohio law.

Upon review, however, the Court agrees with Leatt that Pollack-Nelson’s advertising opinions are inadmissible under *Daubert* and Fed. R. Evid. 702. As noted above, the Supreme Court stated in *Daubert* that when

Faced with a proffer of expert scientific testimony, . . . the trial judge must determine . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.

Daubert, 509 U.S. at 592-93. Pollack-Nelson's opinions do not satisfy this test. As Leatt asserts, and Pollack-Nelson admits, her opinions are not based on any scientific knowledge regarding the existence of a product defect. Rather, Pollack-Nelson admits that for purposes of her opinions, she assumed a product defect solely on the basis of Dr. Burton's report. Accordingly, Pollack-Nelson does not purport to offer testimony based on and expert or "scientific knowledge" that would be helpful to the jury in regard to determining the existence of a product defect. *Leichtamer*, which held that commercial advertising is admissible for purposes of establishing a product defect in a products liability case, is therefore not instructive in determining the admissibility of Pollack-Nelson's proposed "human factors" expert testimony, which does not purport to pertain to the existence of product defect.

Further, plaintiffs have not persuasively demonstrated that the "human factors" opinions and conclusions that Pollack-Nelson offers in her report (and that derive from Pollack-Nelson's assumption that a product defect exists) will assist or aid the jury in understanding or determining plaintiffs' alleged claims. To the contrary, the Court finds that Pollack-Nelson's proposed testimony will not aid the jury. The jury is fully able to assess plaintiffs' claims, including their contentions of Leatt's failure to adequately warn consumers and to recall its product, without the assistance of "expert" testimony of a human factors psychologist.

Defendant's motion to exclude the proposed opinion testimony of Pollack-Nelson is granted. Plaintiffs have not persuasively demonstrated that Pollack-Nelson's testimony will

assist the trier of fact in understanding the evidence or determining any fact in issue.

4. Defendant's Motion to Exclude William F. Kitzes

Plaintiffs' final challenged expert is William F. Kitzes, a lawyer and a Board Certified Product Safety Manager and Hazard Control Manager. Plaintiffs offer Kitzes as an expert in "product safety management" and contend that he will assist the jury in deciding issues central to plaintiffs' claims of negligence, defective design, and failure to warn.

In his report, Kitzes sets out five steps of a system of safety management applied by a "reasonably prudent" product manufacturer: (1) establish a written safety policy; (2) identify and evaluate product hazards; (3) perform an adequate risk assessment, including considering the conditions of use of the product and the environment used; (4) monitor the safety performance after sale and use and take corrective action where necessary; and (5) develop adequate warnings and training to motivate consumers to understand and avoid dangers. (Kitzes Rep. at 5-6). Kitzes then offers the following "opinions" without any further specific analysis:

1. Leatt failed to act as a reasonably prudent manufacturer and distributor to adequately protect motocross riders from the catastrophic risk of injury while wearing the Leatt Moto GPX Brace under foreseeable conditions of use.
2. Leatt has collected and analyzed, through the Leatt Injury Assessment Protocol, reports of well over 100 riders who were injured while wearing the Leatt-Brace during a fall or crash. Leatt has provided 7 injury assessment evaluations concerning significant spinal injury. They have been notified of 5 lawsuits concerning personal injuries sustained while wearing the Leatt-Brace.
3. Leatt promoted the Moto GPX Brace as an "effective neck injury prevention device" and as "the helmet for your neck" to protect riders from catastrophic injury. Yet the "revolutionary" GPX Brace has failed to provide users the level of protection claimed by their advertisements and expected by riders under foreseeable conditions of use. Leatt sponsored racers who promoted the brace as a major advance in rider safety, yet until the rider picks

up or opens the box, there was little, if any, information provided on the limitations of that protection.

4. The Leatt advertising and promotion campaign for the Moto GPX Brace presented a misleading and deceptive “net impression” to Tim Scarvelli and motocross riders that the brace would protect them from neck and spinal injury. The Federal Trade Commission (FTC) defines false advertising as an advertisement that is misleading and fails to reveal material facts. If such misleading and deceptive advertisement can cause serious harm that a consumer could have avoided with accurate information, the advertising is deceptive. A claim can be false and misleading because of what it implies, and the “net impression” of all claims is considered. An ad is deceptive if a consumer is likely to be misled, and the intention of the advertiser is not relevant to the analysis. The “net impression” created by Leatt advertising can lead motocross riders to believe that wearing the GPX Brace will protect them from injury and that failure to wear the brace can result in catastrophic injury. According to the FTC, last minute disclaimers are often ineffective in light of an intensive advertising campaign.

5. Leatt failed to report to the Consumer Product Safety Commission (CPSC) under the Section 15 of the Consumer Product Safety Act and the regulations at 16 CFR 1115 that they had obtained information which reasonably supported the conclusion that the Leatt GPX Brace contains a defect which “could create” a substantial product hazard. Such failure to report deprives the CPSC, on behalf of consumers, the opportunity to evaluate the data while working with the company to substantially reduce the potential for injury.

(*Id.* at 8-10.)

Leatt moves to exclude Kitzes’s opinion testimony for a host of reasons:

- Kitzes’s first opinion is merely a personal opinion because Kitzes does not derive this opinion by addressing any of the factors laid out in Ohio’s Products Liability Act. Further, the first opinion is not supported by a discernible “methodology.”
- Kitzes’s second opinion “is not an opinion at all” but is a statement describing a portion of Leatt’s discovery responses; Kitzes did not have a basis to opine on the topic of Leatt Corporation’s Injury Assessment Protocol because there is no indication in Kitzes’s report that he received, read, or analyzed any of the 100 plus rider reports Leatt produced in discovery; and Kitzes’s statements in this opinion as to other lawsuits are neither relevant nor admissible in the case as there has been no showing that the circumstances of accidents in the other lawsuits are substantially similar to the accident at issue

here.

- Kitzes's third opinion is an inadmissible personal opinion that has no relevance to the legal issues to be decided in this case; Kitzes's report does not "supply a process" by which Kitzes reached this conclusion; and Kitzes furnishes "no method by which he determined or could determine what may be "expected by riders," which is not an issue the jurors will be asked to decide.
- Kitzes's fourth and fifth opinions, which have in common the claim by Kitzes that Leatt violated federal laws (the Federal Trade Commission's regulation of false advertising and the Consumer Product Safety Commission's Section 15 regulation of "substantial product hazard"), should be excluded because they do not relate to claims that either can be are being made in this lawsuit; therefore, these opinions are irrelevant. Further, Kitzes's legal conclusions are wrong, and Kitzes did not derive his opinions about Leatt's advertising from a reliable methodology.¹⁰

Additionally, Leatt points out that other courts have excluded Kitzes's testimony in other cases.

Plaintiffs contend Kitzes's opinion testimony is proper. They argue that Kitzes's testimony is relevant because:

Plaintiff have alleged, among other things, that Leatt failed to exercise reasonable care in the design, testing, manufacture, construction, marketing, product warning and/or modification of Leatt Brace to assure that it was safe for its intended use by consumers. In order to prove their negligence and defect claims, Plaintiffs retained Mr. Kitzes, a product safety consultant, to evaluate whether the principles of product safety management had been adequately applied by Leatt Corporation with regard to the subject brace and to determine whether Leatt's conduct comported with the generally accepted

¹⁰

In this regard, Leatt asserts that Kitzes did not identify any particular testimony to justify his proposed opinions on the effect of Leatt's advertising and his report does not set out any methodology, discussion, or analysis by which he attempts to "(1) identify the advertising that either Scott or Tim Scarvelli actually saw or read before obtaining Scott's brace in 2007; (2) demonstrate how the specific advertising was 'false'; or (3) provide evidence of what Scott or Tim Scarvelli did or thought in reliance on the 'false' advertising."

(Leatt Mem. at 11.)

principles as recognized in the specialized field of Mr. Kitzes' expertise.

Mr. Kitzes' testimony assesses whether Leatt's product safety management measures reasonably anticipated all foreseeable failure modes of the brace and the sufficiency of its process in determining these failure modes. Furthermore, Mr. Kitzes' opinions relating to product safety management provide a framework to the jury for determining whether Leatt acted reasonably in placing the subject brace in the marketplace. These issues of fact are central to Plaintiffs' claims of negligence, defective design, and failure to warn and, as such, are directly relevant to the issues in this case.

(Pltf. Opp. at 4.)

And plaintiffs argue that Kitzes's testimony will be helpful to the jury because the general principles of product safety management are not common knowledge to lay people, and Kitzes's "testimony will assist the jury in deciding an extremely important fact in issue, that is, whether Leatt acted as a reasonably prudent manufacturer in designing, producing, marketing, and adequately warning consumers about potential dangers associated with the subject brace." (Pltf. Opp. at 9.)

Plaintiffs contend Kitzes used a "reliable" methodology to generate his conclusions, stating:

The methodology employed by Mr. Kitze is carefully laid out over eight pages of his report. He begins with an overview of product safety management, describing it as "a system that a reasonably prudent manufacturer puts in place before the first product is conceived to ensure that the final product, along with its warnings, packing, and marketing materials, is reasonably safe" and states that its main function is to serve as a "tool to protect consumers before they purchase products." He also explains that "a product safety audit as outlined by the National Safety Council can be used to test the validity of a company's program and to identify the objective techniques to be applied."

After introducing the system of product safety management, Mr. Kitzes spends two and a half pages outlining the accepted principles of safety analysis that a reasonably prudent manufacturer should apply to ensure its product is reasonably safe. Mr. Kitzes concludes the section detailing his methodology with an excerpt from a Consumer Product Safety Commission (CPSC)

publication, published in 1975, which addresses design review and risk assessment. This publication, updated in 2006, states, “[m]anufacturer’s must assure the safety of consumer products” and identifies the elements of a comprehensive system approach to achieve this stated goal.[”]

It is this system, covered by over four pages of his report, which Mr. Kitzes employed as his methodology.

(*Id.* at 6-7.)

Upon review of Kitzes’s report, however, the Court agrees with Leatt that Kitzes’s opinion testimony is excludable under *Daubert* and Fed. R. Evid. 702. Even acknowledging that Kitzes has expertise in the field of “product safety management” and that such expertise is or could be relevant to some issue or issues raised in the case, there is insufficient information and analysis in Kitzes’s report to conclude that Kitzes employed a “reliable” methodology in reaching his “conclusions” such that his opinions are admissible. The “opinions” Kitzes purports to provide, set forth above, are not cogent (or cogently linked to the issues raised in the case) and are not supported by any discernible rationale or methodology. Kitzes, for example, does not substantively analyze any specific purported conduct (or omission) of Leatt or explain how Leatt’s conduct fell short of any safety management principle. Rather, Kitzes merely makes conclusory statements in his opinions that are devoid of any discernible analysis or methodology and states facts that the jury does not need his help or expertise to determine. Plaintiffs’ arguments in support of Kitzes’s proposed testimony are unpersuasive.

Defendant’s motion to exclude to exclude the proposed expert testimony of Kitzes is granted. The Court finds that Kitzes’s proposed testimony fails to meet the requirements of Fed. R. Evid. 702 and *Daubert*.

5. Plaintiffs' Motion to Exclude Mitchell A. Garber

Plaintiffs, for their part, move to exclude the testimony of Leatt's proposed expert, Dr. Mitchell A. Garber. (Doc. 72.) Dr. Garber is a physician and a biomechanical engineer with years of experience in transportation investigation. In his report, Garber opines among other things that:

4. The thoracic strut of the Leatt brace does not significantly interact with the spinous processes, and, with forward flexion of the head and neck, separates from the back of the user.

5. Though the Leatt brace, by design, reduces the extent of flexion of the cervical spine, Mr. Scarvelli's axial compression spinal injuries would have occurred well before flexion resulted in any significant interaction between the helmet and the brace in this accident.

6. Given the nature of this impact, Mr. Scarvelli's injuries were likely to have occurred with or without the use of the Leatt brace.

(Garber Rep. at 30.)¹¹

Plaintiffs move to exclude the testimony of Dr. Garber, contending that he "is not qualified to give expert opinions on causation" and that his "opinion involving the mechanism of Plaintiff Scott Scarvelli's spine injury does not meet the legal standard set forth in Fed. R. of Evid. 702" and *Daubert*. (Pltfs. Mem. at 1.) Plaintiffs argue that Dr. Garber should be excluded as a witness because

While Dr. Garber is equipped with the scientific knowledge and direct experience to qualify him to opine about the causation of "accidents" involving large vehicles such as tugboats, aircrafts, and motorcoaches, he does not possess the direct experience or the scientific knowledge to opine about the "cause" or mechanism of the spinal injury sustained while wearing a brace designed specifically for dirt bike riders.

¹¹

Thus, Garber, Leatt's physician expert, reached different conclusions than plaintiffs' physician expert, Joseph Burton.

(Pltfs. Mem. at 5.) Plaintiffs contend that Garber's experience and background may qualify him to testify "on matters of medical or human factors and causes of transportation accidents, such as fatigue, perception, medication use, [or] visual impairment," but he is "not qualified to testify on the very specialized and narrow issues of head impact kinematics and resulting spine injury. (*Id.* at 7.) They argue:

Dr. Garber simply does not possess the training or professional experience necessary to be qualified to opine on the mechanism of the spine injury and the role the brace played in causing or preventing injury. He has not conducted any relevant testing or research on head impact and spine injury, has not been involved with any such relevant testing or research, and has not published any literature or such studies or research.

(*Id.* at 8.)

Leatt contends Dr. Garber has the requisite "knowledge, skill, experience, training, or education" necessary to qualify on the matters on which he opines in this case pursuant to Fed. R. Evid. 702, pointing out that he holds degrees in medicine and biomechanical engineering. Further, for fifteen years, Dr. Garber was the only full-time medical officer at the U.S. National Transportation Safety Board where he focused on the "pathology, toxicology, human performance, and biomechanics of bone fracture" and received a prestigious award for his work in the field biomechanics in 2011 from the International Research Council on the Biomechanics of Injury. (Pltf. Opp. at 2-3.) Leatt further disputes plaintiffs' contention that Dr. Garber lacks particularized biomechanical expertise for purposes of his opinions in this case, pointing out that Dr. Garber specifically testified that he had experience looking at the cause and effect of biomechanical injuries while he worked as an accident investigator for the NTSB.

In sum, Leatt asserts that plaintiffs cannot credibly claim that Dr. Garber does not

possess the direct experience or scientific knowledge to analyze the mechanism of spinal injuries. It argues that all of Dr. Garber's opinions were reliably derived, fall within the scope of his education, training, and experience, and are supported by the methods he employed in his report. (Pltf. Opp. at 4.) Plaintiffs did not dispute any of these assertions in a reply brief.

Plaintiffs' motion to exclude Dr. Garber is denied. A review of Dr. Garber's Curriculum Vitae and related materials makes clear that his qualifications in the field are significant and qualify him to opine as to the matters covered in his report.

Conclusion

For the reasons discussed above, Leatt's motions to exclude the proposed opinion testimony by William F. Kitzes (Doc. 54) and Carol Pollack-Nelson (Doc. 70) are granted. All of the remaining pending motions to exclude expert testimony are denied.

IT IS SO ORDERED.

/s/ Patricia A. Gaughan
PATRICIA A. GAUGHAN
United States District Judge

Dated: 7/15/13